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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

APR 2 2 1992

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

ID#: 080803. Atrazine Technical: Product Chemistry. SUBJECT:

> Generic Data. [CBRS: #9030][DP BARCODE: D172008] Jesen S. Onthon

William L. Anthony, Chemist FROM:

Special Review Section II

Chemical Branch II - Reregistration Support

Health Effects Division [H7509C]

Francis B. Suhre, Section Head framis & Author
Special Review Section TT THRU:

Chemical Branch II - Reregistration Support

Health Effects Division [H7509C]

TO: Venus Eagle, PM #71

Reregistration Branch

Special Review & Reregistration Division [H7505C]

Atrazine is a List A Chemical. A Registration Standard and FRSTR were issued for atrazine on 9/85 and 10/88, respectively. The following product chemistry data were submitted under MRID #420-948-01:

Series 61: PRODUCT CHEMISTRY AND COMPOSITION

§61-3 Discussion of the Formation of Impurities

Series 62: ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

§62-1 Preliminary analysis of Product Samples

§62-2 Certification of Ingredient Limits

§62-3 Analytical Methods to Verify Certified Limits

These data were submitted by OXON ITALIA S.p.A., Milano, Italia for their technical atrazine [EPA Reg. #35915-6].

§61-3 Discussion of Formation of Impurities.

See CONFIDENTIAL APPENDIX A for registrants comments on the

unlikelihood of nitrosamine and dioxin formation in their technical product. The potential formation of impurities other than nitrosamines and dioxins were not discussed.

Series 62: ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

§62-1 <u>Preliminary Analysis of Product Samples</u> §62-3 Analysis Methods to verify Certified Limits

See CONFIDENTIAL APPENDIX B for registrants analysis of their atrazine batches.

§62-2 Certification of Ingredient Limits

A signed Certified Statement of Formula [Form OMB #2070-0060] was submitted by the Registrant. However, the upper and lower certified limits for each active ingredient and the upper certified limit for each impurity was not included in the form.

CONCLUSIONS

- (1) Data provided in MRID #420-948-01 do not fulfill the requirements for Product Chemistry Guideline §61-3 [Discussion of Formation of Impurities]. Potential formation of impurities other than nitrosamines and dioxins were not discussed.
- (2) Data provided in MRID #420-948-01 do not fulfill the requirements for §62-1 [Preliminary Analysis of Product Samples] and §62-3 [Analytical Methods to Verify Certified Limits]. The submission did not include a description of the analytical procedures used for determining several components of the technical grade active ingredient nor were experimental data (chromatograms, recoveries, etc.) provided in support of tabulated results. Information (including new data) must be submitted which shows all the impurities >01% in the TGAI, and which demonstrates closure. (Total percentage of identified components for each batch of the TGAI analyzed.)
- (3) Date provided in MRID #420-948-01 do not fulfill the requirements for §62-2 [Certification of Ingredient Limits] because the upper and lower certified limits for each active ingredient and the upper maximum limit for each impurity detected in the technical grade product were not included in the certified Confidental Statement of Formula.

CC: With Confidential Appendix; RF;SF[atrazine];Reviewer; Rey Stol Update, CC: Without Confidential Appendix: Circulation RDI: FBS,4/16/92;MM,4/20/92;EZ,4/21/92.
H7509CX: WLA;Wla;CM-2,Rm 812;X305-6309;4/21/92.

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Description of the product manufacturing process.	
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Identity of the source of product ingredients.	
Sales or other commercial/financial information.	
A draft product label.	
The product confidential statement of formula.	
Information about a pending registration action.	
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The information not included is generally considered comby product registrants. If you have any questions, pleathe individual who prepared the response to your request.	ise contact